PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant:	STEVEN E. WALAK	Confirmation No.:	3380
Serial No.:	10/725,890	Examiner:	Bradley J. Osinski
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Title:	COMPOSITE MEDICAL DEVICE AND METHOD OF FORMING		

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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Thu H. Le-To

MARCH 11, 2011
Date

Dear Sir:

Pursuant to 37 C.F.R. § 41.37, Appellant hereby submits this Appeal Brief in furtherance of the Notice of Appeal filed on November 19, 2010, and of the Notice of Panel Decision from Pre-Appeal Review dated Mailed January 14, 2011 setting a one-month response period ending February 14, 2011. Applicant hereby requests a one-month extension of time, extending the period for response to March 14, 2011.

Appellant authorizes the fee prescribed by 37 C.F.R. § 41.20(b)(2) in the amount of $540.00 to be charged to Deposit Account No. 50-0413.

Please consider this a PETITION FOR ONE-MONTH EXTENSION OF TIME to enter these papers. Permission is hereby granted to charge or credit Deposit Account No. 50-0413 for any errors in fee calculation.

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I. REAL PARTY IN INTEREST

The real party in interest is the assignee of record, SciMed Life Systems, Inc., a corporation organized and existing under and by virtue of the laws of Minnesota, and having a business address of One SciMed Place, Maple Grove, MN 55311-1566. An assignment from the inventor, Steven E. Walak, conveying all right, title and interest in the invention to SciMed Life Systems, Inc. has been recorded at Reel 015182, Frame 0291. A Change of Name from SciMed Life Systems, Inc. to Boston Scientific Scimed, Inc. has been recorded at Reel 018505, Frame 0868.

II. RELATED APPEALS AND INTERFERENCES

There are no other known appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

Claims 1-22, 25-57, 59-70 and 73-78 are pending in the application, of which, claims 28-56 are withdrawn and claims 1-22, 25-27, 57, 59-70 and 73-78 are rejected. Claims 23-24 and 71-72 have been canceled from the application.

Claims 1-9, 11, 13, 15, 16, 18-21, 25-26, 57, 59, 61, 63-64, 66-68, 73, 76 and 77 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over *Ren et al.*, U.S. Patent 6,045,547 (hereinafter "Ren"), in view of *Viera*, U.S. Patent 6,039,699.

Claims 12, 17, 60 and 65 stand finally rejected under 35 USC 103(a) as being unpatentable over Ren and Vera as applied to claims 1 and 57 above, and further in view of O'Brien et al., WO99/58184.

Claims 14 and 62 stand finally rejected under 35 USC 103(a) as being unpatentable over Ren and Viera as applied to claims 1 and 57 above and further in view of Rooney et al., US 6,306,105 (hereinafter "Rooney").

Claims 74, 75 and 78 stand finally rejected under 35 USC 103(a) as being unpatentable over Ren and Viera as applied to claim 1 and further in view of Jones, USPN 5,843,050.

Claims 1-22, 25-27, 57, 59-70 and 73-78 of the application are currently being appealed

IV. STATUS OF AMENDMENTS

No amendment was filed subsequent to final rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER*

The invention relates generally to medical devices, such as catheters and the like, that include a composite shaft or other such structure. In some embodiments, the composite elongated shaft can be constructed by forming the metallic outer portion including the first metallic material about a metallic inner portion including the second metallic material different from the first meet. The second metallic material can be more flexible than the first metallic material. See abstract.

Turning now to independent claim 1, which is directed to a composite medical device (figure 1, reference numeral 110) produced by a process comprising: constructing a metallic composite elongate shaft (figures 1, 2, 4 and 6, reference numeral 110; page 3, lines 24-26; page 4, lines 24-26) by co-drawing or co-extruding (page 8, lines 23-29) a metallic outer portion (figures 2-6, reference numeral 114; page 4, lines 26-27; page 5, lines 14-17) comprising a first metallic material about a metallic inner portion (id. at reference numeral 112) including a lumen therein (figure 2, reference numeral 119; page 8, lines 14-16), the metallic inner portion comprising a second metallic material different from the first material, wherein the second metallic material is more flexible than the first metallic material (page 3,

* The references to the specification and drawings provided herein are exemplary, and are not deemed to be limiting. For simplicity and because the application was restricted to the embodiment of Figures 2 and 3, the references to the specification and drawings are primarily directed towards Figures 2 and 3 and the corresponding description in the specification, but this is not meant to be limiting as support may be found throughout the specification and in many of the Figures.

lines 26-30), and wherein the composite elongate shaft has a distal region (figure 3, reference numeral 116; page 9, lines 19-21) and a proximal region (figure 3, reference numeral 118; page 9, lines 23-25); wherein co-drawing or co-extruding the metallic outer portion about the metallic inner portion forms the composite elongate shaft as a unitary construction (page 8, lines 23-29) and removing a segment of the metallic outer portion from the composite shaft to expose a segment of the metallic inner portion (page 9, lines 4-8).

Claim 2 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein removing the segment of the metallic outer portion (figures 2-6, reference numeral 114; page 4, lines 26-27; page 5, lines 14-17) from the composite shaft to expose the segment of the metallic inner portion (id. at reference numeral 112) includes removing the segment of the metallic outer portion from the composite shaft in the distal region (figure 3, reference numeral 116; page 9, lines 19-21) of the composite elongate shaft (figure 3; page 9, lines 19-21).

Claim 3 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), also including allowing a second segment of the metallic outer portion (figures 2-6, reference numeral 114; page 4, lines 26-27; page 5, lines 14-17) of the composite shaft to remain disposed about a second segment of the inner portion (id. at reference numeral 112) of the composite shaft (figure 3, page 9, lines 23-25).

Claim 4 recites the composite medical device of claim 3 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein allowing the second segment of the metallic outer portion of the composite shaft to remain disposed about the second segment of the inner portion of the composite shaft includes allowing the second segment of the metallic outer portion of the composite shaft to remain disposed about the second segment of the inner portion in the proximal region of the composite elongate shaft (figure 3; page 9, lines 23-25).

Claim 5 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the segment of the metallic outer portion figures 2-6, reference numeral 114; page 4, lines 26-27; page 5, lines 14-17) removed from the distal region of the shaft to expose the segment of the metallic inner portion(id. at reference numeral 112), and also including allowing a second segment of the metallic outer

portion of the composite shaft to remain disposed about a second segment of the inner portion at the distal region of the shaft (page 10, lines 1-11).

Claim 6 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein constructing the composite elongate shaft comprises co-drawing the metallic inner portion with the metallic outer portion to form the composite shaft (page 8, lines 23-27).

Claim 7 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein constructing the composite elongate shaft comprises co-extruding the metallic inner portion with the metallic outer portion to form the composite shaft(page 8, lines 23-27).

Claim 8 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein removing a segment of the metallic outer portion (figures 2-6, reference numeral 114; page 4, lines 26-27; page 5, lines 14-17) includes providing a tapered transition (figure 3, reference numeral 137) between a region in which the metallic outer portion is intact and a region in which the metallic outer portion has been removed (Figure3, page 12, lines 4-12).

Claim 9 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein removing a segment of the metallic outer portion (figures 2-6, reference numeral 114; page 4, lines 26-27; page 5, lines 14-17) comprises grinding a segment of the metallic outer portion from the composite shaft to expose a segment of the metallic inner portion(figures 2-6, reference numeral 112; page 4, lines 26-27; page 5, lines 14-17; page 11, lines 21-25).

Claim 10 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein removing a segment of the metallic outer portion comprises etching a segment of the metallic outer portion from the composite shaft to expose a segment of the metallic inner portion (page 11, lines 4-5).

Claim 11 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic inner portion comprises a nickel-titanium alloy (page 5, lines 14-19).

Claim 12 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic inner portion comprises beta titanium (claim as originally filed).

Claim 13 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic inner portion comprises a super-elastic nickel-titanium alloy (page 5, lines 14-20).

Claim 14 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic inner portion comprises a linear-elastic nickel-titanium alloy (page 5, lines 14-20).

Claim 15 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic inner portion comprises a hollow tube having a length, and the lumen extends along the entire length (Figure 2, reference numeral 119, page 4, lines 28-30; page 8, lines 12-13).

Claim 16 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic outer portion comprises stainless steel, cobalt alloy, Elgiloy, MP35N, tantalum, tungsten, or refractory metal (page 5, lines 14-20).

Claim 17 recites the composite medical device of claim 12 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic outer portion comprises stainless steel, cobalt alloy, Elgiloy, MP35N, tantalum, tungsten, or refractory metal (page 5, lines 14-20).

Claim 18 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the composite medical device comprises a catheter (page 4, lines 16-19; Figure 1).

Claim 19 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the composite medical device comprises a guide catheter (claim as originally filed).

Claim 20 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein removing a segment of the metallic outer portion comprises grinding a segment of the metallic outer portion from a segment of

the metallic inner portion (page 11, lines 21-25), and the process further includes grinding a segment of the metallic inner portion to form a reduced outer diameter region on the metallic inner portion (id.; page 12, lines 14-16).

Claim 21 recites the composite medical device of claim 20 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the reduced diameter region of the metallic inner portion comprises a tapered portion (page 11, lines 18-19).

Claim 22 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein removing the segment of the metallic outer portion includes selectively removing part of the first metallic material to form a pattern of the first metallic material that remains on the shaft (page 10, lines 9-20).

Claim 25 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the composite medical device comprises a hypo-tube catheter, a drug delivery catheter, a therapeutic catheter, a diagnostic catheter or a guide catheter (claim as originally filed.

Claim 26 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic material of the inner portion has a modulus of elasticity that is less than the modulus of elasticity of the metallic material of the outer portion (page 7, lines 7-9, 13-16).

Claim 27 recites the composite medical device of claim 1 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic material of the outer portion has higher tortional rigidity than the metallic material of the inner portion (page 7, lines 7-22).

Claim 57 recites a composite medical device (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26) comprising a metallic composite elongate shaft (figures 1, 2, 4 and 6, reference numeral 110; page 3, lines 24-26; page 4, lines 24-26) including a metallic outer portion (figures 2-6, reference numeral 114; page 4, lines 26-27; page 5, lines 14-17) comprising a first metallic material co-drawn or co-extruded about a metallic inner portion (id. at reference numeral 112) including a lumen defined therein (figure 2, reference numeral 119; page 8, lines 14-16) such that the metallic inner portion and the metallic outer portion are formed together as one unitary construction (page 8, lines 23-29), the metallic inner portion comprising a second metallic material different from the first material, wherein the second

metallic material is more flexible than the first metallic material (page 3, lines 26-30), and wherein the composite elongate shaft has a distal region (figure 3, reference numeral 116; page 9, lines 19-21) and a proximal region (figure 3, reference numeral 118; page 9, lines 23-25); and the distal region of the shaft has a segment of the metallic outer portion removed from the composite shaft to expose a segment of the metallic inner portion (page 9, lines 4-8), wherein the distal region of the shaft is more flexible than the proximal region of the shaft (page 9, lines 19-25).

Claim 59 recites the composite medical device of claim 57 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic inner portion comprises a nickel-titanium alloy (page 5, lines 14-19).

Claim 60 recites the composite medical device of claim 57 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic inner portion comprises beta titanium (claim as originally filed).

Claim 61 recites the composite medical device of claim 57 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic inner portion comprises a super-elastic nickel-titanium alloy (page 5, lines 14-21).

Claim 62 recites the composite medical device of claim 57 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic inner portion comprises a linear-elastic nickel-titanium alloy (page 5, lines 14-21).

Claim 63 recites the composite medical device of claim 57 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic inner portion comprises a hollow tube having a length, the lumen extending along the entire length (Figure 2, reference numeral 119, page 4, lines 28-30; page 8, lines 12-13).

Claim 64 recites the composite medical device of claim 57 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic outer portion comprises stainless steel, cobalt alloy, Elgiloy, MP35N, tantalum, tungsten, or refractory metal (page 5, lines 14-26).

Claim 65 recites the composite medical device of claim 60 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic outer portion comprises

stainless steel, cobalt alloy, Elgiloy, MP35N, tantalum, tungsten or refractory metal (page 5, lines 14-26).

Claim 66 recites the composite medical device of claim 57 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the composite medical device (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26) comprises a catheter (page 4, lines 16-19; Figure 1).

Claim 67 recites the composite medical device of claim 57 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the composite medical device comprises a guide catheter (claim as originally filed).

Claim 68 recites the composite medical device of claim 57 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic material of the inner portion has a modulus of elasticity that is less than the modulus of elasticity of the metallic material of the outer portion (page 7, lines 7-9, 13-16).

Claim 69 recites the composite medical device of claim 57 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the metallic material of the outer portion has higher torsional rigidity than the metallic material of the inner portion (page 7, lines 7-22).

Claim 70 recites the composite medical device of claim 57 (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26), wherein the distal region of the shaft having the segment of the metallic outer portion removed from the composite shaft also includes a second segment of the metallic outer portion that remains on the composite shaft in a pattern (page 10, lines 9-20).

Claim 73 recites a composite medical device (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26) comprising a unitary metallic composite elongate shaft (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26; page 8, lines 23-29) including a metallic outer portion (figures 2-6, reference numeral 114; page 4, lines 26-27; page 5, lines 14-17) comprising a first metallic material formed (page 8, lines 23-29) about a metallic inner portion (id. at reference numeral 112) including a lumen defined therein (figure 2, reference numeral 119; page 8, lines 14-16), the metallic inner portion comprising a second metallic material different from the first material, wherein the second metallic material is more flexible than the first metallic material (page 3, lines 26-30), and wherein the composite elongate shaft

(figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26) has a distal region (figure 3, reference numeral 116; page 9, lines 19-21) and a proximal region (figure 3, reference numeral 118; page 9, lines 23-25); means for providing the distal region with a higher level of flexibility relative to the proximal region (page 9, lines 4-8); and means for providing the proximal region with a higher level of stiffness relative to the distal region (page 9, lines 4-8).

Claim 74 recites a composite medical device (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26) produced by a process comprising constructing a metallic composite elongate shaft (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26; page 8, lines 23-29) by co-drawing or co-extruding a metallic outer portion (figures 2-6, reference numeral 114; page 4, lines 26-27; page 5, lines 14-17) comprising a first metallic material (page 8, lines 23-29) about a metallic inner portion (id. at reference numeral 112) including a lumen therein (figure 2, reference numeral 119; page 8, lines 14-16) such that the metallic inner portion and the metallic outer portion are formed together as one unitary construction (page 8, lines 23-29), the metallic inner portion comprising a second metallic material different from the first material, wherein the second metallic material is more flexible than the first metallic material (page 3, lines 26-30), and wherein the composite elongate shaft (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26) has a distal region (figure 3, reference numeral 116; page 9, lines 19-21) and a proximal region (figure 3, reference numeral 118; page 9, lines 23-25); removing a segment of the metallic outer portion from the composite shaft to expose a segment of the metallic inner portion (page 5, lines 4-8); wherein removing the segment of the metallic outer portion includes selectively removing part of the first metallic material to form a pattern of the first metallic material that remains on the shaft (page 10, lines 9-11); and wherein the pattern is in the form of a helix or spiral, or a series of cells, squares, ovals, rectangles, triangles or circles along the length of a portion of the shaft (page 9 lines 11-15).

Claim 75 recites a composite medical device (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26) comprising: a unitary metallic composite elongate shaft (figures 1, 2, 4 and 6, reference numeral 110; page 4, lines 24-26; page 8, lines 23-29) including a metallic outer portion (figures 2-6, reference numeral 114; page 4, lines 26-27; page 5, lines 14-17) comprising a first metallic material (page 8, lines 23-29) co-drawn or co-extruded about a metallic inner portion (id. at reference numeral 112) including a lumen defined therein (figure

2, reference numeral 119; page 8, lines 14-16), the metallic inner portion comprising a second metallic material different from the first material, wherein the second metallic material is more flexible than the first metallic material (page 3, lines 26-30), and wherein the composite elongate shaft has a distal region (figure 3, reference numeral 116; page 9, lines 19-21) and a proximal region (figure 3, reference numeral 118; page 9, lines 23-25); the distal region of the shaft has a segment of the metallic outer portion removed from the composite shaft to expose a segment of the metallic inner portion, wherein the distal region of the shaft is more flexible than the proximal region of the shaft (page 5, lines 4-8); wherein the distal region of the shaft having the segment of the metallic outer portion removed from the composite shaft also includes a second segment of the metallic outer portion that remains on the composite shaft in a pattern (page 10, lines 9-11); and wherein the second segment of the metallic outer portion that remains on the composite shaft is in the shape of a spiral or helix, a series of cells, squares, rectangles, ovals or circles along the length of a portion of the shaft (page 10 lines 11-15).

Claim 76 recites the composite medical device of claim 1 wherein the step of constructing a composite elongate shaft forms a composite elongate shaft of unitary construction having a bond along the entire length common to both the metallic inner portion and the metallic outer portion (page 8, lines 23-29).

Claim 77 recites the composite medical device of claim 1 wherein during the step of constructing a composite elongate shaft a bond forms between the metallic inner portion and the metallic outer portion at every point of contact between the metallic inner portion and the metallic outer portion (page 8, lines 23-29).

Claim 78 recites composite medical device of claim 1 wherein the segment removed is in the shape of a spiral or helix (page 10, lines 11-15).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 1-9, 11, 13, 15, 16, 18-21, 25-26, 57, 59, 61, 63-64, 66-68, 73, 76 and 77 are unpatentable under 35 USC 103(a) over *Ren et al.*, U.S. Patent 6,045,547 (hereinafter "Ren"), in view of *Viera*, U.S. Patent 6,039,699.

2. Whether claims 12, 17, 60 and 65 are unpatentable under 35 USC 103(a) over Ren and Vera as applied to claims 1 and 57 above, and further in view of O'Brien et al., WO99/58184.

3. Whether claims 14 and 62 are unpatentable under 35 USC 103(a) over Ren and Viera as applied to claims 1 and 57 above and further in view of Rooney et al., US 6,306,105.

4. Whether claims 74, 75 and 78 are unpatentable under 35 USC 103(a) over Ren and Viera as applied to claim 1 and further in view of Jones, USPN 5,843,050.

VII. ARGUMENT

A. CLAIMS 1-9, 11, 13, 15, 16, 18-21, 25-26, 57, 59, 61, 63-64, 66-68, 73, 76 AND 77 ARE PATENTABLE OVER REN ET AL., U.S. PATENT NO. 6,045,547, IN VIEW OF VIERA, U.S. PATENT NO. 6,039,699, UNDER 35 U.S.C. § 103(a).

1. All claim limitations must be considered.

"All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). Claim 1, for example, recites "constructing a composite elongate shaft by co-drawing or co-extruding a metallic outer portion comprising a first metallic material about a metallic inner portion including a lumen therein." As described in the specification on page 8, line 27, "such unitary construction allows the formation of a composite shaft 110 that can be co-drawn and straightened such that the inner portion 112 and the outer portion 114 are formed together as one unitary construction." The structure of this claim element, therefore, is disclosed by neither Ren nor Viera.

Ren is directed towards catheters made of polymer layers, with the possible inclusion of a wire braid or helix as a stiffening member. Viera is directed to a solid metallic core wire that may have a metallic sleeve disposed thereon. Significantly, this sleeve is formed separately and then secured to the core wire by an adhesive, welding, brazing or soldering. Viera, col. 4, ll. 26-29.

The mere substitution of the metallic materials of Ren, with the joining methods taught by Ren of adhesive, welding, brazing or soldering, would not produce the claimed structure. In contrast, constructing a shaft by forming the metallic outer portion about a metallic inner portion creates a composite shaft of unitary construction. See the specification at page 8, lines 23-29. In essence there is a metallic bond between the two layers running the length of the shaft. This metallic composite shaft of two distinct layers is a structural element that is not disclosed in either reference.

The Examiner argues that it would "be obvious to one of ordinary skill in the art to make a catheter of Ren et al using the materials suggested by Viera, in this case metallic inner and outer layers." Final Office Action of September 22, 2010, pg. 3. By making the catheter of Ren, the Examiner means using the material of Viera, the Examiner means making a co-extruded two-layer tube with metallic materials. This is not reasonably suggested by the cited art.

Ren teaches co-extruding polymer materials. Viera teaches adhering two metal layers together using an adhesive, welding, brazing or soldering. Co-extruding metals is much more sophisticated and difficult process and is consequently more expensive and involved than the polymer co-extrusion techniques of Ren or the metal fastening techniques of Viera.

"In view of the cases decided since KSR, one situation when it is important to identify a reason to combine known elements in a known manner to obtain predictable results is when the combination requires a greater expenditure of time, effort, or resources than the prior art teachings. Even though the components are known, the combining step is technically feasible, and the result is predictable, the claimed invention may nevertheless be nonobvious when the combining step involves such additional effort that no one of ordinary skill would have undertaken it without a recognized reason to do so." 2010 KSR Guidelines, 75 FR 53646.

The use of metals in a co-extrusion process resulting in a tubular member requires the expenditure of greater effort and resources. The Examiner has articulated no reason why one of skill in the art would want to go to such greater expense of resources other than to render obvious the claimed invention.

If one were looking only at the disclosures of Ren and Viera, and if one were looking to make the catheter of Ren out of metals as taught by Viera, one would look to the metal fastening techniques as taught by Viera rather than the polymer techniques of Ren to create the catheter. One of skill in the art recognizes that working with polymers is substantially different than working with metal.

A catheter of Ren made with the metals of Viera as well as the metal fastening techniques of Viera has structural differences with the invention of claim 1. "The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product." MPEP 2113 citing *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979). As taught on page 8, lines 23-29 of the application, a co-extrusion or co-drawing process creates a unitary shaft, where the materials are joined as one where they are in contact. In contrast, the bonding processes of Viera would not result in a unitary construction and the bond would not be along the entire length of the shaft.

Independent claim 57 recites "a composite elongate shaft including the metallic outer portion comprising a first metallic material co-drawn or co-extruded about a metallic inner portion including a lumen defined therein" and Independent claim 73 recites "a composite elongate shaft including a metallic outer portion comprising a first metallic material co-drawn or co-extruded about a metallic inner portion including a lumen defined therein." Because these claims contain essentially the same limitation as that discussed with respect to claim 1 above, appellants believe these claims, and those that depend therefrom, are allowable for the reasons discussed above.

Because, when all claim limitations are properly considered, Viera and Ren and do not suggest the desirability of the claimed invention, the Examiner has failed to establish a *prima facie* case of obviousness. As such, claims 1-9, 11, 13, 15, 16, 18-21, 25-26, 57, 59, 61, 63-64, 66-68, and 73 are believed to be allowable over Ren in view of Viera.

B. CLAIMS 12, 17, 60 AND 65 ARE PATENTABLE OVER REN AND VIERA AS APPLIED AGAINST CLAIMS 1 AND 57, FURTHER IN VIEW OF O'BRIEN ET AL., WO99/58184, UNDER 35 U.S.C. § 103(a).

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Because these claims depend from one of claims 1 or 57 and contain additional elements, appellants believe these claims to be allowable for at least that reason. The addition of O'Brien et al. to the prior art under consideration does not remedy the defects discussed above.

C. CLAIMS 14 AND 62 ARE PATENTABLE OVER REN AND VIERA AS APPLIED AGAINST CLAIMS 1 AND 57, FURTHER IN VIEW OF ROONEY ET AL., U.S. PATENT NO. 6,306,105, UNDER 35 U.S.C. § 103(a).

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Because these claims depend from one of claims 1 or 57 and contain additional elements, appellants believe these claims to be allowable for at least that reason. The addition of Rooney et al. to the prior art under consideration does not remedy the defects discussed above.

D. CLAIMS 74, 75 AND 78 ARE PATENTABLE OVER REN AND VIERA AS APPLIED AGAINST CLAIMS 1, FURTHER IN VIEW OF JONES, U.S. PATENT NO. 5,843,050, UNDER 35 U.S.C. § 103(a).

"All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). Claim 74 recites, for example, "constructing a metallic composite elongate shaft by co-drawing or co-extruding a metallic outer portion comprising a first metallic material about a metallic inner portion including a lumen therein such that the metallic inner portion and the metallic outer portion are formed together as one unitary construction." Claim 75 recites "a

unitary metallic composite elongate shaft including a metallic outer portion comprising a first metallic material co-drawn or co-extruded about a metallic inner portion including a lumen defined therein." These claims are therefore allowable over Ren in view of Viera for the reasons stated above. Claim 78 depends from claim 1.

Jones is cited as disclosed a microcatheter having a helical pattern on at least part of the shaft. The addition of Jones does not remedy the deficiencies discussed above in Ren and Viera with respect to claim 1. Therefore, because these claims are directed to unitary shafts having two metallic materials, appellants submit that the claims are allowable over the cited art for the reasons discussed above.

E. CONCLUSION.

For the reasons stated above, claims 1-9, 11, 13, 15, 16, 18-21, 25-26, 57, 59, 61, 63-64, 66-68, 73, 76 and 77 are patentable over Ren et al. in view of Viera, claims 12, 17, 60 and 65 are patentable over Ren and Vera as applied to claims 1 and 57 and further in view of O'Brien et al., claims 14 and 62 are patentable over Ren and Viera as applied to claims 1 and 57 above and further in view of Rooney et al, and claims 74, 75 and 78 are patentable over Ren and Viera as applied to claim 1 and further in view of Jones. The rejection should therefore be overruled.

Respectfully submitted,

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VIII. CLAIMS APPENDIX

1. A composite medical device produced by a process comprising:

constructing a metallic composite elongate shaft by co-drawing or co-extruding a metallic outer portion comprising a first metallic material about a metallic inner portion including a lumen therein, the metallic inner portion comprising a second metallic material different from the first material, wherein the second metallic material is more flexible than the first metallic material, and wherein the composite elongate shaft has a distal region and a proximal region;

wherein co-drawing or co-extruding the metallic outer portion about the metallic inner portion forms the composite elongate shaft as a unitary construction; and

removing a segment of the metallic outer portion from the composite shaft to expose a segment of the metallic inner portion.

2. The composite medical device of claim 1, wherein removing the segment of the metallic outer portion from the composite shaft to expose the segment of the metallic inner portion includes removing the segment of the metallic outer portion from the composite shaft in the distal region of the composite elongate shaft.

3. The composite medical device of claim 1, also including allowing a second segment of the metallic outer portion of the composite shaft to remain disposed about a second segment of the inner portion of the composite shaft.

4. The composite medical device of claim 3, wherein allowing the second segment of the metallic outer portion of the composite shaft to remain disposed about the second segment of the inner portion of the composite shaft includes allowing the second segment of the metallic outer portion of the composite shaft to remain disposed about the second segment of the inner portion in the proximal region of the composite elongate shaft.

5. The composite medical device of claim 1, wherein the segment of the metallic outer portion removed from the distal region of the shaft to expose the segment of the metallic

inner portion, and also including allowing a second segment of the metallic outer portion of the composite shaft to remain disposed about a second segment of the inner portion at the distal region of the shaft.

6. The composite medical device of claim 1, wherein constructing the composite elongate shaft comprises co-drawing the metallic inner portion with the metallic outer portion to form the composite shaft.

7. The composite medical device of claim 1, wherein constructing the composite elongate shaft comprises co-extruding the metallic inner portion with the metallic outer portion to form the composite shaft.

8. The composite medical device of claim 1, wherein removing a segment of the metallic outer portion includes providing a tapered transition between a region in which the metallic outer portion is intact and a region in which the metallic outer portion has been removed.

9. The composite medical device of claim 1, wherein removing a segment of the metallic outer portion comprises grinding a segment of the metallic outer portion from the composite shaft to expose a segment of the metallic inner portion.

10. The composite medical device of claim 1, wherein removing a segment of the metallic outer portion comprises etching a segment of the metallic outer portion from the composite shaft to expose a segment of the metallic inner portion.

11. The composite medical device of claim 1, wherein the metallic inner portion comprises a nickel-titanium alloy.

12. The composite medical device of claim 1, wherein the metallic inner portion comprises beta titanium.

13. The composite medical device of claim 1, wherein the metallic inner portion comprises a super-elastic nickel-titanium alloy.

14. The composite medical device of claim 1, wherein the metallic inner portion comprises a linear-elastic nickel-titanium alloy.

15. The composite medical device of claim 1, wherein the metallic inner portion comprises a hollow tube having a length, and the lumen extends along the entire length.

16. The composite medical device of claim 1, wherein the metallic outer portion comprises stainless steel, cobalt alloy, Elgiloy, MP35N, tantalum, tungsten, or refractory metal.

17. The composite medical device of claim 12, wherein the metallic outer portion comprises stainless steel, cobalt alloy, Elgiloy, MP35N, tantalum, tungsten, or refractory metal.

18. The composite medical device of claim 1, wherein the composite medical device comprises a catheter.

19. The composite medical device of claim 1, wherein the composite medical device comprises a guide catheter.

20. The composite medical device of claim 1, wherein removing a segment of the metallic outer portion comprises grinding a segment of the metallic outer portion from a segment of the metallic inner portion, and the process further includes grinding a segment of the metallic inner portion to form a reduced outer diameter region on the metallic inner portion.

21. The composite medical device of claim 20, wherein the reduced diameter region of the metallic inner portion comprises a tapered portion.

22. The composite medical device of claim 1, wherein removing the segment of the metallic outer portion includes selectively removing part of the first metallic material to form a pattern of the first metallic material that remains on the shaft.

25. The composite medical device of claim 1, wherein the composite medical device comprises a hypo-tube catheter, a drug delivery catheter, a therapeutic catheter, a diagnostic catheter or a guide catheter.

26. The composite medical device of claim 1, wherein the metallic material of the inner portion has a modulus of elasticity that is less than the modulus of elasticity of the metallic material of the outer portion.

27. The composite medical device of claim 1, wherein the metallic material of the outer portion has higher tortional rigidity than the metallic material of the inner portion.

57. A composite medical device comprising:

a metallic composite elongate shaft including a metallic outer portion comprising a first metallic material co-drawn or co-extruded about a metallic inner portion including a lumen defined therein such that the metallic inner portion and the metallic outer portion are formed together as one unitary construction, the metallic inner portion comprising a second metallic material different from the first material, wherein the second metallic material is more flexible than the first metallic material, and wherein the composite elongate shaft has a distal region and a proximal region; and

the distal region of the shaft has a segment of the metallic outer portion removed from the composite shaft to expose a segment of the metallic inner portion, wherein the distal region of the shaft is more flexible than the proximal region of the shaft.

58. The composite medical device of claim 57, wherein the composite elongate shaft is a co-drawn or co-extruded shaft.

59. The composite medical device of claim 57, wherein the metallic inner portion comprises a nickel-titanium alloy.

60. The composite medical device of claim 57, wherein the metallic inner portion comprises beta titanium.

61. The composite medical device of claim 57, wherein the metallic inner portion comprises a super-elastic nickel-titanium alloy.

62. The composite medical device of claim 57, wherein the metallic inner portion comprises a linear-elastic nickel-titanium alloy.

63. The composite medical device of claim 57, wherein the metallic inner portion comprises a hollow tube having a length, the lumen extending along the entire length.

64. The composite medical device of claim 57, wherein the metallic outer portion comprises stainless steel, cobalt alloy, Elgiloy, MP35N, tantalum, tungsten, or refractory metal.

65. The composite medical device of claim 60, wherein the metallic outer portion comprises stainless steel, cobalt alloy, Elgiloy, MP35N, tantalum, tungsten or refractory metal.

66. The composite medical device of claim 57, wherein the composite medical device comprises a catheter.

67. The composite medical device of claim 57, wherein the composite medical device comprises a guide catheter.

68. The composite medical device of claim 57, wherein the metallic material of the inner portion has a modulus of elasticity that is less than the modulus of elasticity of the metallic material of the outer portion.

69. The composite medical device of claim 57, wherein the metallic material of the outer portion has higher torsional rigidity than the metallic material of the inner portion.

70. The composite medical device of claim 57, wherein the distal region of the shaft having the segment of the metallic outer portion removed from the composite shaft also includes a second segment of the metallic outer portion that remains on the composite shaft in a pattern.

73. A composite medical device comprising:

a unitary metallic composite elongate shaft including a metallic outer portion comprising a first metallic material co-drawn or co-extruded about a metallic inner portion including a lumen defined therein, the metallic inner portion comprising a second metallic material different from the first material, wherein the second metallic material is more flexible than the first metallic material, and wherein the composite elongate shaft has a distal region and a proximal region;

means for providing the distal region with a higher level of flexibility relative to the proximal region; and

means for providing the proximal region with a higher level of stiffness relative to the distal region.

74. A composite medical device produced by a process comprising:

constructing a metallic composite elongate shaft by co-drawing or co-extruding a metallic outer portion comprising a first metallic material about a metallic inner portion including a lumen therein such that the metallic inner portion and the metallic outer portion

are formed together as one unitary construction, the metallic inner portion comprising a second metallic material different from the first material, wherein the second metallic material is more flexible than the first metallic material, and wherein the composite elongate shaft has a distal region and a proximal region;

removing a segment of the metallic outer portion from the composite shaft to expose a segment of the metallic inner portion;

wherein removing the segment of the metallic outer portion includes selectively removing part of the first metallic material to form a pattern of the first metallic material that remains on the shaft; and

wherein the pattern is in the form of a helix or spiral, or a series of cells, squares, ovals, rectangles, triangles or circles along the length of a portion of the shaft.

75. A composite medical device comprising:

a unitary metallic composite elongate shaft including a metallic outer portion comprising a first metallic material co-drawn or co-extruded about a metallic inner portion including a lumen defined therein, the metallic inner portion comprising a second metallic material different from the first material, wherein the second metallic material is more flexible than the first metallic material, and wherein the composite elongate shaft has a distal region and a proximal region;

the distal region of the shaft has a segment of the metallic outer portion removed from the composite shaft to expose a segment of the metallic inner portion, wherein the distal region of the shaft is more flexible than the proximal region of the shaft;

wherein the distal region of the shaft having the segment of the metallic outer portion removed from the composite shaft also includes a second segment of the metallic outer portion that remains on the composite shaft in a pattern; and

wherein the second segment of the metallic outer portion that remains on the composite shaft is in the shape of a spiral or helix, a series of cells, squares, rectangles, ovals or circles along the length of a portion of the shaft.

76. The composite medical device of claim 1 wherein the step of constructing a composite elongate shaft forms a composite elongate shaft of unitary construction having a bond along the entire length common to both the metallic inner portion and the metallic outer portion.

77. The composite medical device of claim 1 wherein during the step of constructing a composite elongate shaft a bond forms between the metallic inner portion and the metallic outer portion at every point of contact between the metallic inner portion and the metallic outer portion.

78. The composite medical device of claim 1 wherein the segment removed is in the shape of a spiral or helix.

IX. EVIDENCE APPENDIX

No additional evidence has been presented.

X. RELATED PROCEEDINGS APPENDIX

None